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| 09/662,784 | 09/15/2000 | Malcolm L. Gefter | IMI-044DV3CN | 3152 |

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| EXAMINER |
|---|
| TURNER, SHARON L |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | 13 |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application N . | Applicant(s) | |
|---|---|---|---|
| | 09/662,784 | GEFTER ET AL. | |
| | Examin r | Art Unit | |
| | Sharon L. Turner | 1647 | |

*-- The MAILING DATE of this communication appears n the cover sheet with the c rrespondenc address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disp sition of Claims**

4)☒ Claim(s) *95-110* is/are pending in the application.

4a) Of the above claim(s) *97-100 and 105-110* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *95,96 and 101-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *95-110* are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *15 September 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## *DETAILED ACTION*

### Specification

The specification is objected to because of the following informalities: Appropriate correction is required.

The preliminary amendment filed 9-15-00 has been entered in part. The following amendments have not been entered due to discrepancy in the specification; at p. 5, at line 13, delete "Figure 9", at p. 7, line 18, delete "(SEQ ID NOS:94 AND 95)" and insert (SEQ ID NOS102 AND 103), at p. 7, line 19, delet "Fig. 32" and insert (Fig. 32), at p. 7, line 32, delete "Fig. 37" and insert (Fig. 37), at p. 63, line 15, delete "Figure 15" and insert "Figure 14". Accordingly the Figure legends do not correspond with the Figures.

### *Drawings*

The drawings are objected to because cancellation of Figure 9 necessitates renumbering of the Drawings as appropriate. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification

following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Applicant's should update the continuity data in the first paragraph. It is also noted that entry of the preliminary amendment in the transmittal papers, before the first line results in duplication of certain data. The duplicate data should be canceled by amendment.

> The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994).

In instant case priority is claimed from US Application No. 07/431,565 filed 11-03-1989. However, the disclosure of the '565 application fails to disclose the full length sequence of SEQ ID NO:6 which is instantly claimed in instant claims 95-96 and 101-104. Thus, the disclosure is not sufficient to provide support for the priority claim. The first disclosure of full length SEQ ID NO:6 appears to occur in US Application No. 07/884,718 filed 5-15-1992. Thus, the priority date awarded instant claims 95-96 and 101-104 is that of 5-15-1992. Should applicant traverse the rejection they should note where first disclosure of full length SEQ ID NO:6 is disclosed, the application, page and line number.

**Sequence Requirements**

It is noted that the non-ASCII "garbage" at the end of Applicants CRF copy of the sequence listing has been deleted.

**Election/Restriction**

Applicant's election with traverse of Group I, therapeutic compositions to the extent of SEQ ID NO:6, claims 95-96 and 101-104 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the groups do not differ from each other but are similar in structure function and search and would not place undue burden upon the Examiner. This is not found persuasive because the different SEQ ID Nos define differences in structural constraints in particular with respect to epitopes and therefore are capable of different effects and usage. Because the searches are different each from the other the searches are not co-extensive and a search for a single member would not reveal all pertinent art to the other members.

The requirement is still deemed proper and is therefore made FINAL.

Claims 97-100 and 105-110 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

BdK

**Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 101-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,048,962. Although the conflicting claims are not identical, they are not patentably distinct from each other because the isolated peptides of the '962 patent render obvious the peptides instantly claimed. In particular the '962 patent teaches full length TRFP peptides comprised of two chains with respective sequences of SEQ ID Nos:2 and 4 and SEQ ID Nos:6, 8, 10 and 16 as disclosed. SEQ ID NO:6 of the '962 patent shares 100% sequence identity with instant SEQ ID NO:6. Thus the peptides comprise SEQ ID NO:6, epitopes in common therewith and mixtures thereof as the claims are drawn to peptides which exhibit more than a single epitope (as encompassed by the full length) and which exhibit epitopes of the different sequences as claimed in instant application and the '962 patent. The stimulation index and positivity index of the peptides are disclosed in claims 10-11 of the '962 patent and thus render obvious the same characteristics as claimed in instant claim 102.

Claims 95-96, 101 and 103-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,019,972. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the isolated peptides and compositions of the '972 patent render obvious the peptides instantly claimed. In particular the '972 patent teaches peptides and compositions comprising T cell epitopes consisting of at least 7-30 amino acids of SEQ ID NO:6 corresponding to cat allergen (TRFP) peptides. The peptides and compositions share respective sequences of SEQ ID Nos:2 and 4 and SEQ ID Nos:6, 8, 10 and 16 as disclosed. SEQ ID NO:6 of the '972 patent shares 100% sequence identity with instant SEQ ID NO:6. Thus the peptides and compositions of the '972 patent comprise SEQ ID NO:6, epitopes in common therewith and mixtures thereof as instantly claimed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 95-96, 101-102 and 104 rejected under 35 U.S.C. 102(a) as being anticipated by Morgenstern et al., PNAS 88:9690-9694, 1991.

Morgenstern et al., teach the amino acid sequence of FeldI, the major allergen of the domestic cat. The teachings include a therapeutic composition comprising an isolated polypeptide which comprises at least part of a sequence of Seq ID NO:6 and shares and epitope in common therewith as the peptide of Morgenstern is 98.6 % identical to SEQ ID NO:6, differing only in that it lacks the first two peptide residues D and T, see in particular col. 2, p. 9690-col. 1, 9691, in particular anti-peptide antisera

produced via chemically synthesized peptides conjugated to keyhole limpet hemocyanin effective to produce an antibody response. The composition comprises a mixture as more than a single peptide is included in the composition. The peptide inherently provides for those characteristics of claim 102 as the peptide shares the epitopes noted in instant specification to exhibit the claimed characteristics, see in particular Figures 21-24. Thus, the reference teachings anticipate the claimed invention.

Claims 95-96 and 101-103 are rejected under 35 U.S.C. 102(b) as being anticipated by Littler et al., J. of Virol., 64(2):714-722.

Littler et al., teach identification, cloning and expression of the Major Capsid Protein gene of HHV-6. The MCP protein residues 354-360 share 100% identity with instant SEQ ID NO:6 residues 103-109 which define an epitope of at least 6 amino acids. The recombinantly produced peptides were electroeluted and inoculated three times i.p. with 10 ug of protein and then once i.v. with 2 ug protein. The proteins produced antibodies reactive with HHV-6 samples and the peptide was detected from serum antibodies from infected patients. The composition comprises a mixture as more that a single peptide is included in the composition. As the peptides meet the structural limitations of the claims and are administered to animals producing an immunogen specific response, the reference teachings inherently anticipate a therapeutic composition comprising the peptide. The peptide compositions are the same and thus necessarily provide for those characteristics of a therapeutic composition as claimed. Similarly as the isolated peptides are the same as claimed, they necessarily provide for

the properties of claim 102. Thus, the reference teachings anticipate the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 95-96 and 101-104 are directed to an invention not patentably distinct from claims 1-19 of commonly assigned U.S. Patent No. 6,048,962 and from claims 1-26 of commonly assigned 6,019,972 as set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned '962 and '972, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case

qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Claims 95-96 and 101-104 rejected under 35 U.S.C. 103(a) as being unpatentable over 6,048,962 and 6,019,972.

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference

are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2). As set forth above the invention is obvious in light of the '962 and '972 patents as the patents and instant application are each drawn to isolated peptides and compositions of SEQ ID NO:6, peptides sharing epitopes with SEQ ID NO:6 and mixtures of peptides comprising peptides sharing epiotopes of SEQ ID NO:6. The the issued patents render the claimed peptides and therapeutic compositions obvious to one skilled in the art.

Claim 103 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morganstern et al., PNAS, 88:9690-9694, 1991 in view of Sibson et al., WO94/01548 (1-20-1994), pp. 1-20 and 613-614.

Morganstern et al., teach as set forth above. Morganstern et al., additionally teach the cDNA sequence encoding the polypeptide of claim 101.

However, Morganstern et al., do not teach the isolated polypeptide according to claim 101 produced recombinantly.

Sibson et al., disclose the advantage of recombinant peptide production by cDNA's as opposed to other labor intensive forms of isolation. Sibson teaches that it is generally useful to place a desired cDNA sequence into an expression vectior, hostcell

and express the encoded protein as well as to raise antibodies to proteins encoded by such cDNA's, see in particular pp. 8-13, the recombinant DNA technique providing the advantage of an unlimited supply of easily isolatable protein.

Thus, it would have been prima facie obvious to the person of ordinary skill in the art at the time the invention was made to use the cDNA of Morganstern to produce the peptides of cat allergen via recombinant techniques and to use such peptides in the production of antibodies thereto for the purposes of producing tolerance and to identify those individuals allergic to cats. One of skill in the art would have expected success given the high skill in the art of recombinant DNA technology, the similarity of peptides produced recombinantly and chemically and the ability to stimulate antibodies which peptides produced using recombinant DNA technology. Thus, the cumulative reference teachings render the invention obvious to one skilled in the art.

Claim 104 is rejected under 35 U.S.C. 103(a) as being unpatentable over Littler et al., J. of Virol., 64(2):714-722 in view of Hirschmann et al., US Patent No. 3,846,399 Nov. 5, 1974.

Littler et al., teach as set forth above.

However, Littler et al., do not teach synthesis of the isolated polypeptide of claim 101 produced via chemical synthesis.

Hirschmann et al., teach a process for controlled stepwise chemical synthesis of peptides, see in particular Abstract, claims 1-9. The process provides the advantage of producing chemically pure polypeptides without the need for further purification, see in particular col. 2, lines 20-30, col. 8, lines 64-68.

Thus, it would have been prima facie obvious to the person of ordinary skill in the art at the time the invention was made to use the process of chemical synthesis as taught by Hirschmann to produce the peptides of cat allergen. One of skill in the art would have expected success given the high skill in the art of chemically synthesizing amino acid peptides, the similarity of peptides produced recombinantly and chemically and the ability to stimulate antibodies with such peptides without the requirement of further purification from cell culture. The purity would ensure proper antigenicity as recognized by the reference teachings. Thus, the cumulative reference teachings render the invention obvious to one skilled in the art.

**Status of Claims**

No claims are allowed.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
July 28, 2002